March 13, 2020

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Expanding State-Approved Diagnostic Tests

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

It is the policy of the United States to take proactive measures to prepare for and respond to public health threats, including the public health emergency involving Coronavirus Disease 2019 (COVID-19), which was declared by the Secretary of Health and Human Services (the "Secretary") on January 31, 2020, pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d). Our response must include heightened coordination among Federal, State, local, and tribal agencies, and we must offer States the flexibility they need to care for their citizens. In accordance with this principle, the Food and Drug Administration, in coordination with the State of New York, allowed the State flexibility in expediting State-approved COVID-19 testing.

Should additional States request flexibility to authorize laboratories within the State to develop and perform tests used to detect COVID-19, the Secretary shall take appropriate action, consistent with law, to facilitate the request.

You are authorized and directed to publish this memorandum in the Federal Register.

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